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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/635,366

08/06/2003

Jeffrey M. Vitullo

3600/268

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7590

05/09/2006

AMSTER, ROTHSTEIN & EBENSTEIN LLP
90 PARK AVENUE
NEW YORK, NY 10016

EXAMINER

RODRIGUEZ, CRIS LOIREN

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/635,366

Applicant(s)

VITULLO ET AL.

Examiner

Cris L. Rodriguez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: There is a typo error in "aid". Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 5, 14, 15, 17-19, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Pande (US 4,753,765).

Pande discloses a catheter having the elements as claimed. With respect to claims 22-24, it is common knowledge the use of a needle having a hub in combination with a catheter for introduction of catheters into the body.

4. Claims 1, 5-18, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson (US 5,702,372).

Nelson discloses a catheter having the elements as claimed. With respect to claims 22-24, it is common knowledge the use of a needle having a hub in combination with a catheter for introduction of catheters into the body.

5. Claims 1-7, 9-15, 17, 18, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Quinn et al (US 6,387,052).

Quinn discloses a catheter having a stiffening section 404 as claimed. With respect to claims 22-24, it is common knowledge the use of a needle having a hub in combination with a catheter for introduction of catheters into the body.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8, 16, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn et al.

Quinn discloses the invention substantially as claimed except for the stiffening coating having a thickness not exceeding about 0.08mm, and the sleeve being made out of PET. The instant disclosure describes this dimension as being merely preferable, and does not describe it as contributing any unexpected result to the catheter. As such this parameter is deemed matters of design choice (lacking in any criticality), well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. With respect to the PET material, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Quinn's sheath 404 with a PET material, since the selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325, U.S. 327, 65 USPQ 297 (1945).

Response to Arguments

8. Applicant's arguments filed January 30, 2006 and February 27, 2006 have been fully considered but they are not persuasive.

9. In regards to applicant's arguments that Pande does not teach a "stiffening section of predetermined length disposed a predetermined distance proximally of said distal end", the examiner disagrees. Figure 2 shows a proximal section 22 where includes a rigid inner sheath 27 that makes the proximal section stiffer than the distal section 23. Therefore, it meets the claims.

10. In regards to applicant's arguments that Nelson and Quinn do not teach a "stiffening section of predetermined length disposed a predetermined distance proximally of said distal end", the examiner disagrees. Nelson's proximal section inner liner includes two layers, which together creates a higher stiffness than the distal end. Quinn's proximal section 100 may include a plurality of layers (figs. 2, 4A, 7, and 10). The combination of layers makes the proximal section stiffer than the distal section. Therefore, it meets the claims.

11. In regards to applicant's arguments that Quinn does not disclose the stiffening section made out of PET. The examiner agrees. However, the instant disclosure describes the selection of PET as being merely preferable, and does not describe it as contributing any unexpected result to the catheter (other than providing stiffness). One of ordinary skill in the art would have selected any other material for the same purpose. As such the selection of PET is deemed matters of design choice (lacking in any

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criticality), well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is 571-272-4964. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 4, 2006


Cris L. Rodriguez
Primary Examiner
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